

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Docket No. 400140)

In re the Application of:

DONALD K. JONES et al.

Serial No.: 09/880,506

Filed: June 13, 2001

For: OCCLUDING VASCULATURE OF A  
PATIENT USING EMBOLIC COIL WITH  
IMPROVED PLATELET ADHESION

To: Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Art Unit: 3743

Examiner Kathryn Odland

RECEIVED

MAY 26 2004

TECHNOLOGY CENTER R3700

**DECLARATION UNDER 37 C.F.R. SECTION 1.131**

I, Vladimir Mitelberg, declares as follows:

1. I am a co-inventor of the invention disclosed and claimed in the above identified application.

2. I have worked in the field of biomedical engineering, including embolization devices, for over eight years and in mechanical engineering for over twenty years.

3. It is my understand that U.S. Patent No. 6,280,457 to Wallace et al., filed June 4, 1999, has been cited by the Patent and Trademark Office in support of rejections of claims 1-4, 6-14, 16, 17, 20, and 27 of the above-identified application.

4. The invention of this application was made prior to June 4, 1999, the date of filing of U.S. Patent No. 6, 280,457. More specifically, the invention was made and completed, and actually reduced to practice, all in the United States of America, prior to June 4, 1999, as evidenced by the attached exhibits.

5. Exhibit A is a date-redacted copy of an invention record disclosure signed by Donald Jones and me. Exhibit A reports on work performed by us and/or under our direction and control in the United States of America prior to June 4, 1999, in connection with making embolic coils for occluding the vasculature of a patient, which devices were made and reduced to practice before June 4, 1999.

6. With respect to Exhibit A (the invention record) referred to in paragraph 5 above, the photographs set forth in the last page of this invention record were taken by Donald Jones of the roughened coils prior to submitting them for evaluation. The page having the number 028122 shows service requests. The picture on the bottom is a service request in which the coils were submitted for evaluation. Four photomicrographs were taken as indicated by the middle box and these four microphotographs were the results of the service requests. These photomicrographs are on the page of Exhibit A following the service requests. All of these photographs and service requests were taken and made prior to June 4, 1999.

7. Exhibit B are date-redacted copies of experiments performed on baboons, in connection with occluding the vasculature of the baboons, which experiments were performed before June 4, 1999.

8. The work referred in paragraph 7 above, included ex-vivo tests outside of the body using the baboon. A silicone tube was connected to the artery of the baboon. Blood flow was through the silicone tube and back to the baboon. In the silicone tube, aneurysms were formed on the tube itself. A delivery catheter was used to place roughened embolic coils inside of the aneurysms, with the help of a pusher mechanism. Live blood was run through the system and radioactive platelets accumulated on the

coils. The coils used were textured 5 mm. complex coils. By using a gamma camera imager, the radioactivity was measured. Non-textured coils were also used. It was found that there were greater amount of platelets on the roughened coils then on the non-roughened coils. From these experiments we were able to conclude that the introduction of the textured coils in the aneurysm would enhance platelet adhesion.

9. In view of my experience in biomedical engineering (including embolization devices) prior to June 4, 1999, I was confident that the vasculature of a patient could be successfully occluded by providing a plurality of embolic coils having a proximal portion that is held by the detachment portion and a distal portion, with the proximal portion that is held by the detachment portion being relatively smooth and the distal portion having a relatively textured surface. I found that the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting. As a result of the experiments, I was confident that the embolization device having a roughened surface was suitable for placement in a catheter for being conventionally implanted with an introducer having a detachment portion to provide improved platelet adhesion compared to a non-textured surface, to promote clotting. Accordingly, in my view, the invention was reduced to practice on a date prior to June 4, 1999, because I was confident that clinical versions of the prototype could be sterilized and clinically used with success to embolize aneurysms in patients.

10. I hereby declare that all statements made herein and of my own knowledge are true, and that all statements made on information and belief are believed to be true; and I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issued therefrom.

Date: May 11-2004

V. Mj-  
Vladimir Mittelberg

PATENT

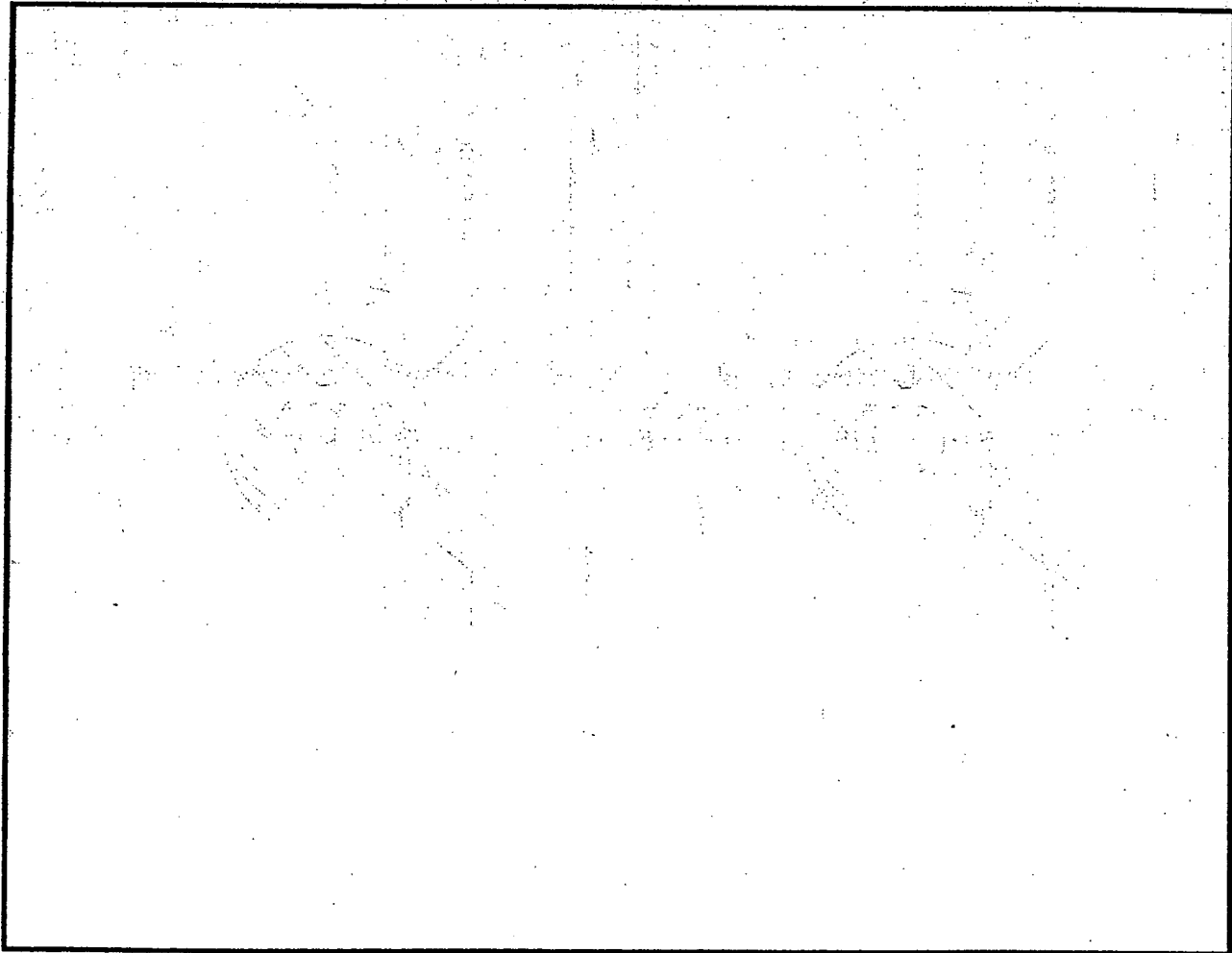
DEPARTMENT

**Cordis**

00/140

**DESCRIPTIVE TITLE: Coil Surface Modification**

- I. **INSTRUCTIONS:** This form should be typed, except for the signatures and dates. Disclose only one invention on this Invention Disclosure form, and complete the entire form as fully as possible. Forward the completed form to the Legal Department, signed and dated by all inventors and two witnesses. Refer to this Invention Disclosure by the number assigned to it when receipt is acknowledged. Attach additional sheets if more space is required. Each original piece of paper must be signed and dated by every inventor and by each witness.
- II. **ILLUSTRATION:** *Include a drawing, sketch, photograph, flow chart, or preferably an engineering quality printout of the invention.*



Name & Signature of Inventor(s):

Date

Witnesses

Date

V. H. H. G.  
Donald E. H. H.

E. H. H. G.  
H. H. H. G.

**EXHIBIT A**

**III. EXPLANATION OF INVENTION:** *Describe the invention completely, including all essential elements.*

The invention is a surface modified embolization coil. The surface has been texture by abrasion or "sand blasting". Fifty-micron diameter alumina particles were used to texture the surface of the platinum tungsten wire used to form the coils. It is believed that the textured surface provides improved platelet adhesion thus promoting clotting and subsequent endothelialization. SEM micrographs and optical pictures of the textured vs. non-textured are attached. Testing using radiolabeled platelets was conducted to evaluate an ex vivo aneurysm model. In the model, aneurysms treated with textured coils were compared to aneurysms treated with non-textured coils. The textured coils showed an increase in the platelet deposition of about 50% over the non-textured coils.

**IV. NOVEL FEATURES AND ADVANTAGES:** *What is new that was not previously known, and why is this important.*

Other surface modification techniques such as coating or ion implantation require expensive and elaborate equipment to modify the coils which add an additional component. This method does not impart any new materials to the coil that would require new biocompatibility testing and can be done inexpensively.

**V. MODIFICATIONS:** *Describe all possible modifications or alternate embodiments.***VI. RELATED DOCUMENTS:** *List all known relevant art references (patents, publications, commercially available products, etc.). Please supply copies of the documents, if available.*

Patents:

Publications:

Signature of Inventor(s):

Date:

Witnesses:

Date:

V. Hing

Donald E. Green

E. Hing  
Donald E. Green

VII. INVENTORS:

DEPARTMENT

Donald K. Jones

First Inventor's Full name (Please type:)

Signature: Donald K. Jones

Date:       

Vladimir Mittelberg

Second Inventor's Full Name (Please type:)

Signature: V. Mittelberg

Date:       

VIII. WITNESSES: This invention was disclosed to and understood by:

Full Name of First Witness (Please type: Eric Cheng)

Signature: Eric Cheng

Date:       

Full Name of Second Witness (Please type:)

Boris Shkolnik

Signature: Boris Shkolnik

Date:       

IX. ADDITIONAL INFORMATION:

Invention is recorded on page(s):        of Notebook No.:        dated:       

Earliest date:        and place: CES where inventors first thought of the present invention.

First written description (date and present location):       

First sketch of the invention (date and present location):       

Earliest date:        and place:        where first operating model was completed.

Present location of model:       

Earliest date of use of the invention (actual or contemplated):       

Earliest shipping date (actual or contemplated):

## Service Request

Job number, assigned by  
supplying organization 32027

Requestor	To <u>CPOA, EPL LAB</u>	Project/Charge _____
	From (organization) <u>CE</u>	Date required _____
	Location _____	
	For information contact <u>PETER GUINONES</u>	<u>x 81020</u>
	Description of request <u>8667A</u>	
	<u>PLEASE PROVIDE SEM PHOTOS</u> <u>OF SURFACE OF COILS PROVIDED</u> <u>FOR ROUGHNESS EVALUATION.</u>	
Requested by <u>P. Guinones</u>	Date _____	
Approved by _____	Date _____	

Supplier	Date received _____
	Labor cost _____
	Material cost _____
	Purchased Materials, services or equipment required <u>notebook 92071-46</u>
	Completion date _____
	Comments <u>Electron optical micrographs were taken</u> <u>of each sample at low &amp; high</u> <u>magnifications to show surface</u> <u>roughness conditions.</u>
Estimate by <u>John Daub</u>	Date <u>1/1/86</u>

Approvals	Cost and completion date accepted by requestor _____
	Signature _____ Date _____
	Comment _____
	_____
	Supplier acceptance by <u>BR</u> Date <u>1/1/86</u>



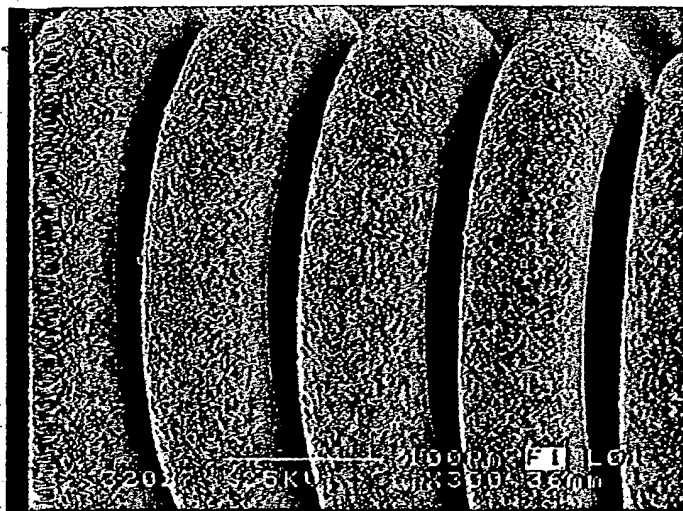


Figure 1-(233x) Sample with rough surface

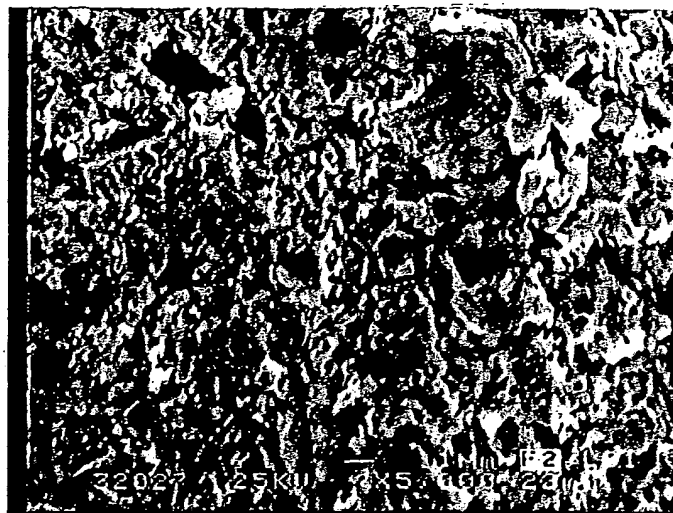


Figure 2-(3880x) Sample with rough surface

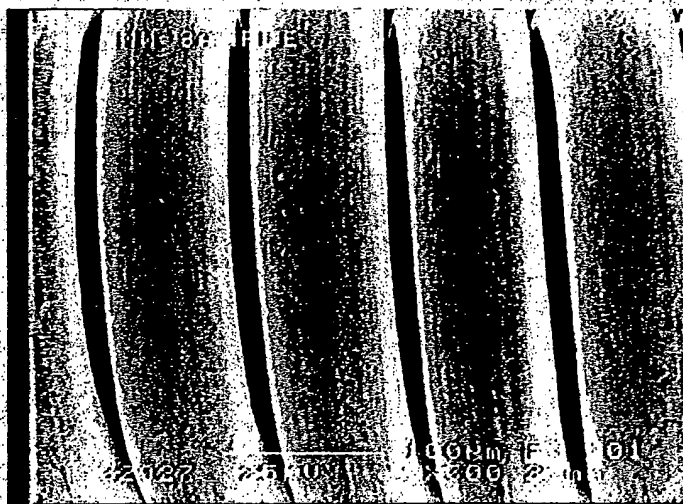


Figure 3-(233x) Sample "MW" with smooth surface.

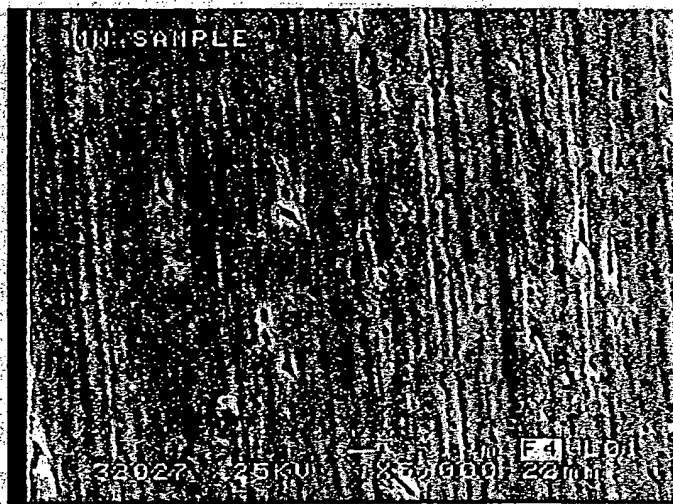


Figure 4-(3880x) Sample "MW" with smooth surface.

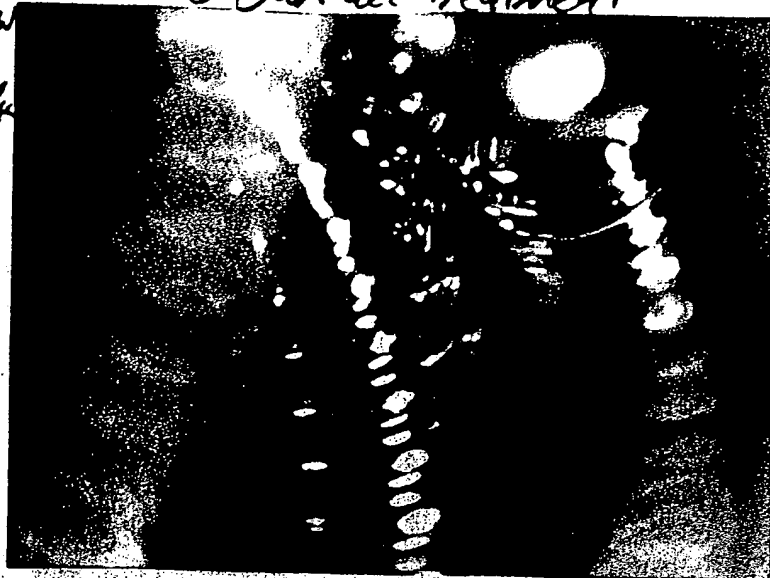
*Double force*

40 X Mag

.003" thick

5mm  
Complex  
(20-mil)

No Surface Treatment



PAT

DEPA

DKP

40 X Mag

.003" thick

5mm  
Complex  
(20-mil)

Surface Treatment



20-mil  
Fibre

Surface Abraded Using AcumBRAGE - 5 21ml3  
50 micron blend of Al<sub>2</sub>O<sub>3</sub> (Part No. AP105)

DKP



Baboon B384right  
Date

Computer  
Data Partition  
Camera  
ROI (device)  
Window  
Energy

A3  
A341  
GE  
8 x 10  
15%  
172  
247  
low  
med  
word  
byte

Study Description

Aneurysm Run #7 textured 5mm dim. complex  
coils. Tail from Aneu. #1 extended 130mm.  
Tail from Aneu. #2 extended 180mm

Collimator

Iodine

Remarks

#2	Time	Min	CPM	ROI	CPM	bkg	Thrombus	Standard	Plts x10 <sup>9</sup>
5	216	169	47.00	0.000511	0.02				
10	255	224.00	31.00	0.000511	0.02				
15	267	255.00	12.00	0.000511	0.01				
20	428	341.00	87.00	0.000511	0.04				
25	551	431.00	120.00	0.000511	0.08				
30	665	583.00	82.00	0.000511	0.04				
35	902	798.00	104.00	0.000511	0.05				
40	1020	792.00	228.00	0.000511	0.12				
45	1170	892.00	87.00	0.000511	0.04				
50	1260	929.00	331.00	0.000511	0.17				
55	1300	947.00	353.00	0.000511	0.18				
60	1330	964.00	368.00	0.000511	0.19				
65	1360	998.00	362.00	0.000511	0.18				
70	1440	998.00	442.00	0.000511	0.23				
75	1510	985.00	525.00	0.000511	0.27				
80	1540	1020.00	520.00	0.000511	0.27				
85	1740	1100.00	640.00	0.000511	0.33				
90	1620	1040.00	580.00	0.000511	0.30				
95	1540	1000.00	540.00	0.000511	0.28				
100	1490	1050.00	440.00	0.000511	0.22				
105	1800	988.00	612.00	0.000511	0.31				
110	1600	892.00	708.00	0.000511	0.36				
115	1600	956.00	644.00	0.000511	0.33				
120	1680	903.00	777.00	0.000511	0.40				
125	1650	954.00	698.00	0.000511	0.36				
130	1680	892.00	788.00	0.000511	0.40				
135	1680	860	820.00	0.000511	0.42				
140	1770	806	964.00	0.000511	0.49				
145	1740	790	950.00	0.000511	0.49				
150	1700	844	856.00	0.000511	0.44				

Pit Cnt Pre 314  
Pit Cnt Post 267  
WBC 8.7  
Hct Pre 41.10%  
Hct Post 38.00%  
Flow (ml/min) 100 clamp

Whole Blood 171188  
Plasma 21908  
Fraction 92.5%  
Free 7.5%  
Volume (cc) 3

Blood Std CPM 2285  
Bkg CPM 291  
Bkgd CPM 1 1994  
CPM in-plts 1843.696  
CPM/ml in-plts 614.5654  
FINIAL 0.000511

Time	Min	CPM	CPM	bkg	Thrombus	Standard	Plts x10 <sup>9</sup>
155	1650	824	826.00	0.000511	0.42		
160	1760	858.00	902.00	0.000511	0.48		
165	1780	888.00	894.00	0.000511	0.48		
170	1800	852.00	948.00	0.000511	0.48		
175	1780	788.00	992.00	0.000511	0.51		
180	1780	838.00	942.00	0.000511	0.48		
185	1880	852.00	1028.00	0.000511	0.53		
190	1850	888.00	962.00	0.000511	0.49		
195	1850	758.00	1092.00	0.000511	0.56		
200	1680	840.00	840.00	0.000511	0.43		
205	1680	744.00	936.00	0.000511	0.48		
210	1750	788.00	962.00	0.000511	0.49		
215	1720	848.00	872.00	0.000511	0.45		
220	1610	738.00	872.00	0.000511	0.45		
225	1740	794.00	946.00	0.000511	0.48		
230	1770	832.00	938.00	0.000511	0.48		
235	1700	778.00	922.00	0.000511	0.47		
240	1660	780.00	880.00	0.000511	0.45		

**Computer  
Data Partition**

## Study Description

Aneurysm Run #1 untextured 5mm dlm. complex colls. Tail from Aneu. #1 stopped 1.25" from aneu. #2. Tail from Aneu #2 extended 16"

**flow stopped at 1hr 25min - shunt was flushed**

Remarks

ROI: ROI:

43 43X48 CPM

Min	CPM	CPM h <sub>0</sub>	Thromb <sub>h0</sub>	Standard	Pits x 10 <sup>3</sup>
0	1000	1000	1000	1000	1000
1	1000	1000	1000	1000	1000
2	1000	1000	1000	1000	1000
3	1000	1000	1000	1000	1000
4	1000	1000	1000	1000	1000
5	1000	1000	1000	1000	1000
6	1000	1000	1000	1000	1000
7	1000	1000	1000	1000	1000
8	1000	1000	1000	1000	1000
9	1000	1000	1000	1000	1000
10	1000	1000	1000	1000	1000
11	1000	1000	1000	1000	1000
12	1000	1000	1000	1000	1000
13	1000	1000	1000	1000	1000
14	1000	1000	1000	1000	1000
15	1000	1000	1000	1000	1000
16	1000	1000	1000	1000	1000
17	1000	1000	1000	1000	1000
18	1000	1000	1000	1000	1000
19	1000	1000	1000	1000	1000
20	1000	1000	1000	1000	1000
21	1000	1000	1000	1000	1000
22	1000	1000	1000	1000	1000
23	1000	1000	1000	1000	1000
24	1000	1000	1000	1000	1000
25	1000	1000	1000	1000	1000
26	1000	1000	1000	1000	1000
27	1000	1000	1000	1000	1000
28	1000	1000	1000	1000	1000
29	1000	1000	1000	1000	1000
30	1000	1000	1000	1000	1000
31	1000	1000	1000	1000	1000
32	1000	1000	1000	1000	1000
33	1000	1000	1000	1000	1000
34	1000	1000	1000	1000	1000
35	1000	1000	1000	1000	1000
36	1000	1000	1000	1000	1000
37	1000	1000	1000	1000	1000
38	1000	1000	1000	1000	1000
39	1000	1000	1000	1000	1000
40	1000	1000	1000	1000	1000
41	1000	1000	1000	1000	1000
42	1000	1000	1000	1000	1000
43	1000	1000	1000	1000	1000
44	1000	1000	1000	1000	1000
45	1000	1000	1000	1000	1000
46	1000	1000	1000	1000	1000
47	1000	1000	1000	1000	1000
48	1000	1000	1000	1000	1000
49	1000	1000	1000	1000	1000
50	1000	1000	1000	1000	1000
51	1000	1000	1000	1000	1000
52	1000	1000	1000	1000	1000
53	1000	1000	1000	1000	1000
54	1000	1000	1000	1000	1000
55	1000	1000	1000	1000	1000
56	1000	1000	1000	1000	1000
57	1000	1000	1000	1000	1000
58	1000	1000	1000	1000	1000
59	1000	1000	1000	1000	1000
60	1000	1000	1000	1000	1000
61	1000	1000	1000	1000</	

[illegible]

3	143	103	42.00	0.000089	0.03
10	152	155	2.00	0.000530	0.02

10	162	163	-3.00	0.000689	0.00
15	220	104	25.00	0.002660	0.00

13	227	194	33.00	0.000689	0.02
20	240	227	2.00	0.000990	0.00

20	240	237	3.00	0.000689	0.00
25	222	242	94.00	0.000580	0.06

29	323	242	81.00	0.000889	0.06
20	324	207	24.00	0.000680	0.20

30	33.1	24.00	0.000689	0.02
25	30.9	5.100	0.000680	0.04

33	396	344	34.00	0.000688	0.04
10	444	104	12.00	0.006880	0.02

40	444	40	43.00	0.000689	0.03
45	506	306	140.00	0.000590	0.09

49	395	395	110.00	0.0000889	0.08
50	528	408	122.00	0.000886	0.08

50	336	400	132,00	0,0000000	0,00
55	575	161	144,00	0,0000000	0,00

55	373	401	114.00	0.000689	0.08
60	623	478	155.00	0.000890	0.11

60	633	4/8	153.00	0.000689	0.11
65	669	4/8	182.00	0.000580	0.13

33	008	489	162.00	0.000889	0.13
30	660	542	148.00	0.000560	0.10

70	500	512	146.00	0.000689	0.10
75	800	583	232.00	0.000690	0.10

73	600	363	237.00	0.000689	0.16
80	814	528	266.00	0.000002	0.30

89	814	328	286.00	0.000000	68889	0.20
85	892	544	220.00	0.000000	212	

85	883	844	239.00	0.000889	0.18
00	020	045	200.00	0.000000	0.20

90	938	616	322.00	0.000689	0.22
05	804	850	874.00	0.000000	0.00

95	924	850	274.00	0.000689	0.19
400	850	680	274.00	0.000689	0.19

100	958	688	27030	0.000689	0.19
105	958	688	27030	0.000689	0.19

105	922	694	228.00	0.000689	0.16
440	824	874	228.00	0.000689	0.16

710	964	6/4	290.00	0.000689	0.20
445	880	8/4	285.00	0.000689	0.20

116	986	664	322.00	0.000889	0.22
108	450	250	225.00	0.000889	0.22

120	959	652	307.00	0.000689	0.21
105	882	882	307.00	0.000689	0.21

125	897	666	231.00	0.000689	0.16
100	870	688	230.00	0.000688	0.16

130	8 1/2	660	212.00	0.000689	0.15
105	10	540	200.00	0.000689	0.15

135	998	700	295.00	0.000689	0.20
145	998	700	295.00	0.000689	0.20

140	1010	686	324.00	0.000689	0.22
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145	1030	754	276.00	0.000689	0.19
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150	986	704	282.00	0.000689	0.19
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**Abstract**

A3	172
A341	247
GE	low
8 x 10	med
15%	word
	byte

Plt Cnt Pre	295
Plt Cnt P st	204
WBC	11.5
Hct Pre	45.40%
Hct Post	42.10%
Flow (ml/min)	100/clamp

Whole Blood	121465
Plasma	16014
Fraction	92.8%
Free	7.2%
Volume (cc)	3

Blood Std CPM	1672
Bkg CPM	291
Bkgd CPM 1	1361
CPM In-plts	1281.589
CPM/ml In-plts	427.1963
FINAL	0.000691

ROI[illegible]

Whole Blood	121465
Plasma	16014

Free	7.2%
------	------

Volume (cc) 3

M-1	1381	...
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427:1963

[illegible]